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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/458,019	06/01/95	JOHNSON	E A-6274-1
EXAMINER			

HM31/0410
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LILLING, H	
ART UNIT	PAPER NUMBER

1651 24
DATE MAILED: 04/10/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on APRIL 01, 1998
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 25-34 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 25-34 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

Ser No. 08/458019

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

15. Receipt is acknowledged of the request for reconsideration and the declaration filed April 01, 1998.

16. Claims 25-34 remain present in the instant application.

5 Claims 1-24 were previously canceled.

17. Claims 25-34 **stand** rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 5,356,810. Although the conflicting
10 claims are not identical, they are not patentably distinct from each other because the patented claims are within the scope of the claimed subject matter.

15 The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re*
20 *Thornington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

25 A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

30 Effective January 1, 1994, a registered attorney or agent of record may sign November 25, 1997 November 25, 1997 the assignee must fully comply with 37 CFR 3.73(b).

It is noted that there is one inventor in common with the patent and the application, see MPEP 800-13, rev 1 Sept 1995, chart IIB-conflicting claims between APPLICATION AND A PATENT.

The arguments submitted have been deemed not to be persuasive since the filing date is not an issue in a Double Patenting of the Obvious-type.

According to the chart indicated above, this Examiner cannot set-up an interference to settle the conflicting claims unless there is an error in the Manual pertaining to this flow sheet.

The arguments submitted by Applicant on April 01, 1998 have been considered but this Examiner is bound by the procedures outlined above that is in the MPEP. There is no leeway for this Examiner to change the procedure or to disregard the above action. The instant claims and the patented claims are not drawn to the same invention but is within the guidelines of double patenting of the obviousness type. The request that "...the only possible course of action the Examiner can pursue is to withdraw the rejection." cannot be possible but Applicant can request the Board of Appeals to overcome the rejection which is based on an impossible position placed on Applicant set-up by the MPEP chart in which one of the inventors is in common with two applications in which the applications are not commonly owned.

19. Claims 25-34 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention as enabling for the claimed microorganisms in accordance with the U.S. Rules of Deposits.

It is apparent that the additional strains are required to practice the claimed invention(s) as recited in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the

specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of these additional strains. See 37 C. F. R. 1.802.

5 If a deposit has not been supplied or made under the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over
10 his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements, See 37 CFR
15 1.808.

20 If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her
25 signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

30 b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

35 c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

40 d) a viability statement in accordance with the provisions of 37 CFR 1.807;

and

e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

5 In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification, See 37 CFR 1.803-37 CFR 1.809 for additional explanations of these requirements.

10 The prior arguments are not persuasive for one of ordinary skill in the art to reproduce all of the mutants encompassed by the claimed inventions since the claims are drawn to products and not processes.

15 Will accept product by process claims to claim all additional strains not deposited

20. Claims 25-34 are rejected under 35 U.S.C. § 112, first paragraph as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make.

25 The following decisions which may be pertinent to the claimed language which may be extremely broad for the microorganism, see: In re Fisher, 168 USPQ 18, 24 (June 11 1970)

30 Such improvements, while unobvious from his teachings, are still within his contribution, since the improvement was made possible by his work. It is equally apparent, however, that he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. 112. that paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.....In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

40 In view of the broad claimed language, the above statement:

45 It is equally apparent, however, that he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. 112. that paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art..

Further decision, see Fiers v. Sugano 25 USPQ2d. 1601. The decision clearly states:

5 "Claiming all DNA's that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived." This above statement is complete concordance with the above decision to In re Fischer. Applicant is absolutely not
10 entitled to the broad claimed language for the "mutant Phaffia" which "requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity." Also, stated "We thus determined that, irrespective of the complexity or simplicity of the method of isolation employed,
15 conception of a DNA, like conception of any chemical substance, requires a definite of that substance other than by its functional utility." Applicant does not teach in the instant specification any and all mutant strains to produce pigments at a certain level but only specific mutant strains.

20 The arguments that the scope of the claims are enabling in view of the alleged screening methods to obtain astaxanthin mutants is not fully persuasive. As indicated above, if the claims are drawn to product by processes, the claims would be considered favorably for allowance. The scope of the claims are broader than the enabling and the rejection of the
25 broad claimed language is in accordance with the above decision of In re Fisher Fischer and

Fiers v. Sugano.

30 The declaration has been considered but the declaration is not commensurate in scope with the broad claimed inventions.

A product by process as well as deposits in accordance with the U.S. Patent Office Rules of Deposit would be sufficient to remove the above rejections.

35 21. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

40 (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 25-34 stand rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over claims of U.S. Patent No. 5,356,810.

5 22. No claim is allowed.

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10 A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date
15 the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is (703) 308-2034 and fax number (Art Unit 1651) is (703) 305-7939. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

10

15 H.J.Lilling: HJL
(703) 308-2034
Art Unit 1651
April 08, 1998



HERBERT J. LILLING
PATENT EXAMINER
GROUP 1600 ART UNIT 1651